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Inventor(s): PATZER CHARLES R;; VEDDER KENT B;; FRANK THOMAS P ;

Applicant(s): MEDEX INC (US) ;

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ABSTRACT:

A dual valve system provides a needleless site (10) that has the advantage of a slit septum valve (12) with a secondary check valve (14) to minimize leakage through the slit septum valve (12) due to back-pressure.

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(71) Applicant: MEDEX, INC. [US/US]; 3637 Lacon Road, Hillard, OH 43026 (US).

(72) Inventors: PATZER, Charles, R.; 12762 Fridley Road, Ashville, OH 43103 (US). VEDDER, Kent, B.; 35 East Tulane Road, Columbus, OH 43202 (US). FRANK, Thomas, P.; 975 Stuart Court, Neenah, WI 54956 (US).

(74) Agents: GROSSMAN, Kurt, L. et al.; Wood, Herron & Evans, 2700 Carew Tower, Cincinnati, OH 45202 (US).

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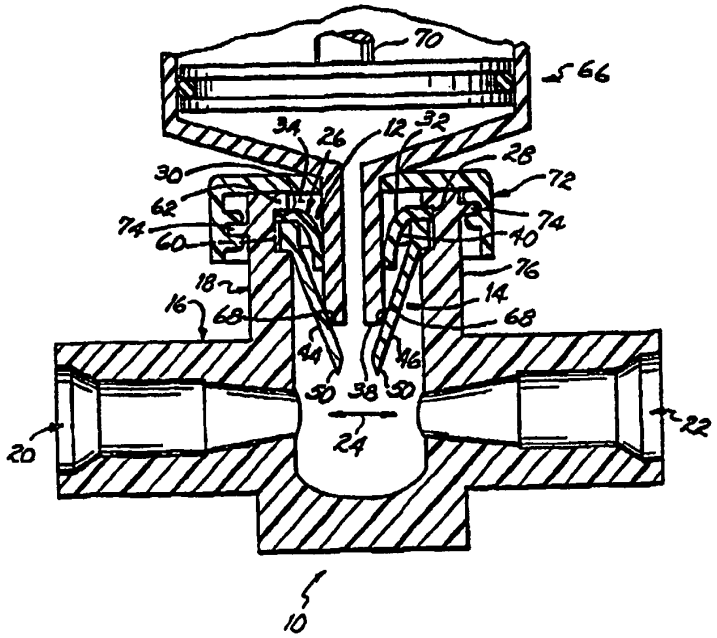

(57) Abstract

A dual valve system provides a needleless site (10) that has the advantage of a slit septum valve (12) with a secondary check valve (14) to minimize leakage through the slit septum valve (12) due to back-pressure.

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SLIT SEPTUM NEEDLELESS SITE WITH CHECK VALVE

Background of the Invention

I. Field of the Invention

The present invention relates to medical sites through which fluid may be injected into or withdrawn from a patient without requiring use of sharp needles.

II. Description of Prior Art

In many medical situations, it is typical to provide a fluid-filled (e.g., saline) line coupled to a patient's circulatory system via a catheter inserted into the patient such as through the arm. A site is coupled in series with the fluid-filled line to provide access to the patient's circulatory system without further puncturing the patient such as with additional needles or catheters or the like. The site has a valve, such as a rubber septum or the like, through which access to the fluid line is by piercing through the septum with a needle, for example. When access is

made, medications may be injected into the patient through the site and fluid line. Similarly, blood samples may be taken from the patient by withdrawal through the site. Examples of such uses are shown in United States Patent Nos. 4,874,377; 5,148.811; 5,203,775; 5,221,271; and co-pending application serial number 08/003,790, filed January 13, 1993, the disclosures of all of which are hereby fully incorporated herein by reference.

As shown in those patents, it is possible to inject medicines into. or to withdraw blood from. the patient through the site rather than by a further needle stick of the patient. But, as discussed in aforementioned U.S. Patent No. 5,203,775, the use of sharp needles, even with sites, presents hazards to the medical personnel using the sites due to the risk of needle sticks which could transmit disease.

The risk of needle sticks is greatly reduced when blunt cannulas. such as the distal plastic end of a typical syringe, can be used to access the fluid line through the valve of the site rather than a sharp needle. And while various proposals have been made to permit use of blunt cannulas. none have apparently met with much success for one reason or another.

One proposal for eliminating needles involves use of a slit septum as the site valve. The slit septum opens under pressure of a blunt cannula thereagainst to allow the blunt cannula to pass into and through the slit of the septum and into communication with the fluid line. While a slit septum has certain advantages in the drive to eliminate needles. it is not

without a serious drawback. In particular, the slit across the septum tends to weaken the valve such that it may not be rigid enough to withstand back-pressure from the fluid line when the cannula is removed. In such an event, the integrity of the valve is jeopardized which could result in fluid leakage from the valve with the attendant undesirable risks of infection and/or disease transmission.

Summary of the Invention

The present invention provides a slit septum valve that may be utilized with a blunt cannula but which does not suffer the drawback of a weakened valve that cannot withstand back pressure when closed. To this end, and in accordance with the present invention, a one way or back check valve is situated between the slit septum and the fluid path. The check valve withstands back pressure from the fluid line when the slit septum is not opened so as to prevent fluid from backing up against the back side of the slit septum, yet allows fluid to flow from the slit septum to the fluid path under pressure such as from a syringe or other source of fluid directed through the slit septum and against the check valve. Yet further, the check valve is situated relative the slit septum such that insertion of a blunt cannula into and through the slit septum will also cause the check valve to open such as by a portion of the blunt cannula impacting against the check valve to deform and forcibly hold same open and permit two-way fluid communication therethrough.

By virtue of the foregoing, there is thus provided a medical site which has the advantage of a slit septum in that blunt cannulas may be

utilized, but which does not suffer the drawback of leakage which might normally be expected to occur with a slit septum. These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and description thereof.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and, together with a general description of the invention given above, and the detailed description given below, serve to explain the principles of the invention.

Fig. 1 is a cross-sectional view of a T-shaped site incorporating a slit septum and check valve in accordance with the principles of the present invention;

Fig. 2 is a cross-sectional view of the site of Fig. 1 shown with a blunt cannula therein for the purpose of explaining operation of the sample site of Fig. 1;

Fig. 3 is a top view of the site of Fig. 1;

Fig. 4 is a cross-sectional view of a cylindrical site incorporating a slit septum and check valve like that of the sample site of Fig. 1;

Fig. 5 is a cross-sectional view of a Y-shaped site incorporating a slit septum and check valve like that of the site of Fig. 1;

Fig. 6 is a cross-sectional view of the valve portion of a site incorporating an alternative embodiment of a combined slip septum/check valve in accordance with the principal of the present invention: and

Fig. 7 is a schematic view of a system incorporating the site of Fig. 1 for purposes of explaining use of the invention.

Detailed Description of the Drawings

With reference to Figs. 1 and 3 there is shown a site 10 incorporating a slit septum valve 12 and a check valve 14 in accordance with the principles of the present invention. Site 10 has a plastic (e.g. polycarbonate or Dow Isoplast) housing 16 defining valve port 18 and fluid ports 20, 22. A fluid path 24 is defined between fluid ports 20, 22 with valve port 18 connected thereto between ports 20, 22 to define a T-shaped cross section to housing 16.

Slit septum valve 12 is formed of resilient material, such as polyisoprene rubber, and comprises a disk 26. The peripheral edge 28 of disk 26 is captured in groove 30 of valve port 18 such that the upper surface 32 of disk 26 is generally flush with the distal edge or opening 34 of valve port 18 to allow slit septum valve 12 to be cleaned with a gauze pad (not shown), for example, wiped thereacross. A slit 36 is formed in disk 26 which slit is normally closed by the resilience of disk 26 but which may be opened under pressure of a blunt cannula 38 inserted therethrough (see Fig. 2).

In order to provide back-pressure withstand to the back surface 40 of slit septum 12, resilient polyisoprene rubber check valve 14

is provided between disk 26 and fluid path 24. Check valve 14 is advantageously a duckbill valve having a pair of confronting lips 44, 46 that converge towards each other as they extend from the slit septum valve 12 to the fluid path 24 to define a slit 48 therebetween at their distal edges 50. Cylindrical walls 52 (only one shown) interconnect lips 44, 46 along their outer edges. Flange 54 is formed at the upper end of the lips to secure check valve 14 within valve port 18 such as within groove 30 along with disk 26 of slit septum valve 12. To provide a stable hold on check valve 14, and for concentricity, a plurality of ribs 60 (e.g., five) are equidistantly spaced around the peripheral edge of groove 30 adjacent the outer periphery of flange 54 situated therein to thus hold lips 44, 46 in proper alignment through valve port 18.

Groove 30 may be provided by molding it into valve port 18, by folding over top lip 62 at distal edge 34, or by providing two separate pieces which are glued or ultrasonically welded together to capture disk 26 and flange 54 therebetween. Although shown as separate components, slit septum valve 12 and check valve 14 could be molded as one component with the outer edge of disk 26 also defining flange 54. Alternatively, disk 26 and flange 54 could be held in separate grooves of housing 16 to situate check valve 14 between slit septum valve 12 and fluid path 24.

As will be readily appreciated, check valve 14 normally provides only one-way fluid communication between slit septum valve 12 and fluid path 24. That is, fluid can normally only flow from distal

opening 34 of valve port 18 through lips 44, 46 of valve 14 to fluid in path 24, but not vice versa as pressure from fluid path 24 against lips 44, 46 will tend to seal them closed. In this way, back-pressure from fluid path 24 is generally prevented from reaching the back surface 40 of disk 26 of slit septum valve 12 to thus minimize the likelihood that back-pressure will cause leakage at slit septum 12. But two-way fluid communication can still be provided where necessary as will now be described.

With reference to Fig. 2, it can be seen that check valve 14 is situated relative slit septum valve 12 such that blunt cannula 38 (e.g., the blunt end of syringe 66), when it passes into and through slit 36 of disk 26, also impacts against the interior sidewalls of lips 44, 46 as at 68 to thus deform valve 14 and forcibly hold lips 44, 46 apart enough to keep check valve slit 48 open whereby fluid may flow either into or from fluid path 24. Thus, when site 10 is used to inject medications, for example, into fluid path 24, pressure (such as from pushing plunger 70 into syringe 66) forces the medications into fluid path 24. Similarly, where fluid is to be withdrawn from fluid path 24, back pressure in fluid path 24, or external suction (such as caused by withdrawing plunger 70) will cause fluid, such as a blood sample, to flow from fluid path 24 into and through check valve 14 and blunt cannula 38 as desired.

In order to hold blunt cannula 38 to site 10, blunt cannula 38 is typically provided with a Luer-threaded nut 72 thereabout. Associated with site 10 are Luer flanges 74 to threadably receive the threads of nut 72 thereon. Thus, as cannula 38 is inserted into slit septum valve 12, rotation

of nut 72 tightens it down onto flanges 74 to secure cannula 38 to site 10. Flanges 74 may be provided by the split Luers or wings as shown in aforementioned U.S. Patent No. 5,203,775, or by mating female Luer threads, or portions thereof, formed on the exterior sidewall 76 of valve port 18 as shown in Figs. 1-3.

It will be appreciated that the slit septum/check valve arrangement of the present invention is not limited to T-shaped sites. Other site constructions could be employed such as where fluid path 24 is defined between valve port 18 and a single fluid port 20 such that housing 16' generally defines a cylindrical site 10' as shown in Fig. 4. Alternatively, housing 16" may be formed as a Y-site 10"as shown in Fig. 5.

With reference to Fig. 6, an alternative valve construction is shown in which the duckbill check valve is formed as an integral part of the slip septum valve. To this end, a unitary valve piece 100 of resilient material, such as rubber, is formed having a disc-like top half 102 with its peripheral edge 104 captured in groove 106 formed in site housing 108 such as by cooperation of housing ledge 110 and cap piece 112 welded to housing 108 (or by bending over an extended top lip (not shown) of housing 108). The upper surface 114 of valve piece 100 is generally flush with cap piece 112 for cleaning as in the case of valve 12. A slit 116 is formed in and through top half 102 to define a slit septum valve like valve 12.

The lower half of valve 100 is provided with an annular ring 120 that sits against annular recess 122 and shelf 124 of housing 108 to support valve 100 therein and help urge valve half 102 into the closed position shown in Fig. 6. Also, formed below top half 102 and extending therefrom adjacent slit 116 are a pair of duckbill lips 130, 132 which function as a check valve. Thus, when valve 100 is closed, as shown in Fig. 6, lips 130, 132 are urged together such that there is an effective extension 134 of slit 116. Lips 130, 132 merge into ring 120 along arcuate underside 136 of valve top 102 to assist in urging lips 130, 132 closed.

In the closed position of lips 130, 132, back-pressure from fluid path 24 below valve 100 bears against lips 130, 132 to assist in forcibly holding them closed to thus minimize the likelihood that back-pressure will cause leakage at slit 116.

When the blunt cannula 38 (see Fig. 2) is pressed against valve top 114, it will cause slit 116 to open to thus pass therethrough. The impact of cannula 38 is also transmitted to lips 130, 132 to forcibly hold them apart while cannula 38 is within slit 116 such that fluid may flow in either direction between cannula 38 and fluid path 24 of site 100 in the same manner as occurred with site 10 described above. Site 100 may have ports to define a T-shape, Y-shape or cylindrical shape as above-described.

Medical sites constructed in accordance with the present invention, such as site 10, may be utilized in a closed blood pressure monitoring/blood sampling system 200 shown in Fig. 7. System 200 may be as described in aforementioned U.S. Patent No. 5,048,537. As seen in

Fig. 7, catheter 202 inserted into a patient's blood vessel is connected by tubing 204 to port 20 of sample site 10. The other port 22 of site 10 is connected via tubing 206 to stopcock 208 and flush valve 210. Intermediate stopcock 208 and flush valve 210 is a pressure sensor 212. Flush valve 210 is connected via tubing 214 to stopcock 216 and thence via tubing 218 to a source 220 of saline. As a consequence, when stopcocks 208 and 216 are properly positioned, sample site 10 is in-line between saline source 220 and catheter 202 so that saline may flow therethrough and allow blood pressure monitoring by blood pressure sensor 212. Sensor 212 is coupled to blood pressure monitor 222 via sensor lead 224 as is well understood. As is also well known, saline source 220 may be pressurized by pressure infuser 226 and its associated squeeze bulb 228 and may also be flow controlled through roller clamp 230.

In use, when it is desired to deliver medication to the patient, cannula 38 of medication-filled syringe 66 is merely inserted through valve port 18 to open at least slit septum valve 12. Plunger 70 is manipulated to force the medication through valve 14 and into fluid path 24 for delivery to the patient. Thereafter, cannula 38 is removed allowing valve 14 to close under back-pressure from fluid line 24 and for slit septum valve 12 to close by its own resilience. If it is desired to obtain a blood sample, stopcock 216 is operated to connect catheter 202 to reservoir 240 through stopcock 216 which also disconnects catheter 202 from saline source 220. Blood from the patient will then flow out of catheter 202 and towards reservoir 240 pushing saline ahead of the blood. After blood

240 pushing saline ahead of the blood. After blood flows into and through site 10, stopcock 208 may be manipulated to stop further flow of fluid and a whole blood sample taken by inserting blunt cannula 38 through valve 12 and against valve 14 so that an open channel for fluid communication is established between syringe 66 and fluid path 24. The blood sample is then withdrawn by manipulation of syringe plunger 70 as is well known.

After the sample is taken and cannula 38 withdrawn, stopcocks 208 and 216 may be manipulated to restore the catheter-to-saline source connection with valve 14 closing off valve port 18 from leakage while blood, remaining in system 200 downstream of stopcock 216, is caused to be driven back into the patient.

While the present invention has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, it is not intended to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. For example, check valve 14 could be separated from slit septum valve 12 with lips 44, 46 extending into fluid path 24. Additionally, flow directors as shown in aforementioned U.S. Patent No. 5,221.271 and/or co-pending application serial no. 08/003,790 could be provided. Similarly, ports 20, 22 could have Luer lock arrangements associated therewith. Although slits 36 and 48 (and 116) are shown as extending across housing 16 (normal to flow path 24), either or both of valves 12 and 14 (or valve 100) could be rotated to position slot 36 and/or 48 (and 116) differently. The invention

in its broadest aspects is therefore not limited to the specific details, representative apparatus and method, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the general inventive concept.

Having described the invention, what is claimed is:

1. A needleless site (10) for use with a male luer connector (72) having a male luer taper portion (38), the site comprising a housing (16,108) having a valve port (18) with an opening (34) and luer connecting structure (74) for mating with said male luer connector (72), a fluid path (24) in the housing coupled to the valve port (18), and a normally-closed slit septum valve member (12,100) in the valve port (18) between the opening (84) of the port and the fluid path (24) and being sufficiently resilient to allow passage of the taper portion (38) therethrough, characterised by a check valve (14,130,132) situated between the slit septum valve member (12,100) and the fluid path (24) for normally providing one-way fluid communication from the slit septum valve member (12,100) to the fluid path (24) but not vice versa whereby the male luer connection (72) may be connected to the luer connecting structure (74) such that the taper portion (38) of the male luer connector is received into the valve port (18) and through the slit septum valve member (12,100) and also opens the check valve (14,130,132) for two-way fluid communication between the male luer taper portion (38) and the fluid path (24).

2. A needleless site (10) comprising a housing (16,108) having a valve port (18) with an opening (34), a fluid path (24) in the housing coupled to the valve port (18), and a normally-closed valve member (12,100) situated in the valve port to selectively restrict access from the opening (34) to the fluid path (24), characterised by a one-way

check valve (14,130,132) situated between the normally-closed valve member (12,100) and the fluid path (24).

3. A needleless site (10) comprising a housing (16,108) having a valve port (18) with an opening (34), a fluid path (24) in the housing coupled to the valve port (18), and a valve system (12,14,100,130,132) in the valve port between the opening (34) of the port and the fluid path (24), characterised in that the valve system has an upper portion valve member (12,100) with a normally-closed slit (36,116) and a lower duckbill valve portion (14,130,132) with a pair of duckbill lips (44,46,130,132) extending from the upper portion and being normally urged together to define an extension of the normally-closed slit (36,116).

4. A needleless site as claimed in claim 3 wherein the normally-closed slit (36,116) extends through the upper portion (12,100) of the valve system.

5. A needleless site as claimed in either claim 3 or claim 4 wherein the valve system includes a support ring (120) held in the housing (16,108).

6. A needleless site as claimed in claim 5 further characterised by the support ring (120) and duckbill lips (44,46,130,132) merging in an arcuate underside (136) of the valve system upper portion.

7. A needleless site as claimed in any of claims 3, 4, 5 or 6 further characterised in that the valve upper and lower portions are formed as a one-piece valve.

8. A needleless site as claimed in either claim 1 or claim 2 wherein the check valve (14,130,132) and the normally-closed valve member (12,100) are each formed from a resilient material.

9. A needleless site as claimed in any of claims 2, 3, 4, 5, 6, 7, or 8 (when dependent from claim 2) further comprising luer structure (74) associated with the housing (16,108) and positioned relative the valve port (18) to receive the luer threads of a luer lock associated with a blunt cannula inserted into the slit septum valve member (14,100) through the valve port (18).

10. A needleless site as claimed in any of claims 1, 2, 8 or 9 (when dependent from claim 2) wherein the check valve (14,130,182) is formed separately from the normally-closed valve member (12,100).

11. A needleless site as claimed in any of claims 1, 2, 8, 9 (when dependent from claim 2) or 10 wherein the normally-closed valve member (12,100) and check valve (14,130,132) are formed as one integral piece.

12. A needleless site as claimed in any of claims 1, 2, 8, 9 (when dependent from claim 2), 10 or 11 further characterised in that the check valve (14,130,132) includes a duckbill valve with lips (44,46,130,132) directed towards one another along a path defined between the normally-closed valve member (12,100) and the fluid path (24).

13. A needleless site as claimed in any of claims 3, 4, 5, 6, 7, 9 (when dependent on any of claims 3, 4, 5, 6 or 7) or 12 wherein the housing (16,108) includes a groove (30) and the duckbill valve includes a flange (54) within the groove, further characterised in that the housing includes projecting structure (60) in the groove (30) adjacent a peripheral edge of the flange (54) for aligning the lips (44,46,130,132).

14. A needleless site as claimed in any preceding claim further comprising a pair of fluid ports (20,22) associated with the housing (16,108) and defining the fluid path (24) therebetween, the valve port (18) being coupled to the fluid path (24) between the fluid ports (20,22).

15. A needleless site as claimed in claim 14 wherein the housing (16,108) has a T-shaped cross-section.

16. A needleless site as claimed in claim 14 wherein the housing (16,108) has a Y-shaped cross-section.

17. A needleless site as claimed in any preceding claim further comprising a fluid port (20) associated with the housing (16,108) wherein the fluid path (24) is defined along a generally straight line between the fluid port (20) and the valve port (18).

18. A needleless site as claimed in any preceding claim wherein the normally-closed valve member (12,100) is situated in the valve port (18) with an exposed surface (32,114) extending across the opening (34) whereby to be cleaned by wiping thereacross.

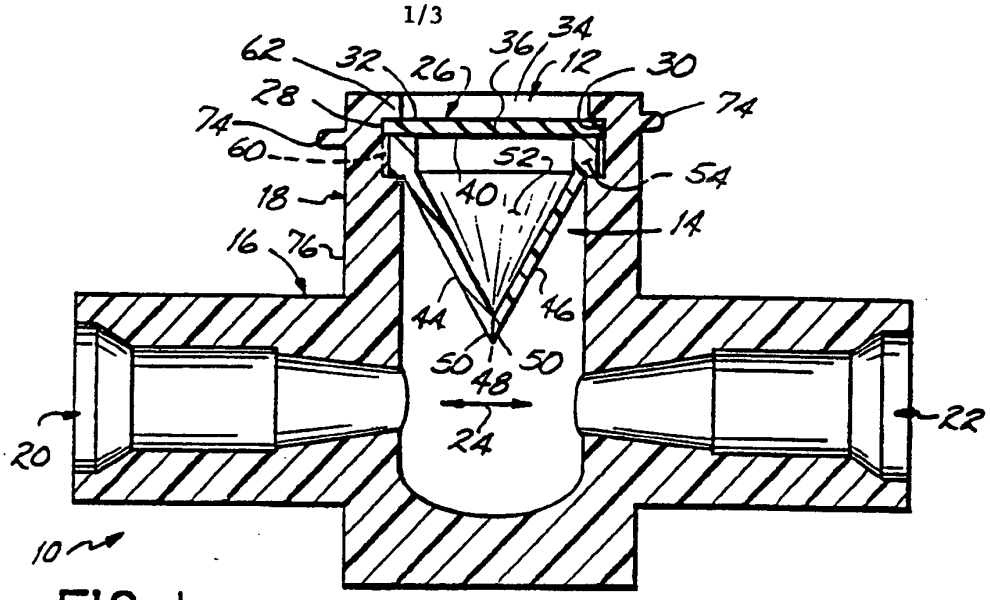
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FIG. 1

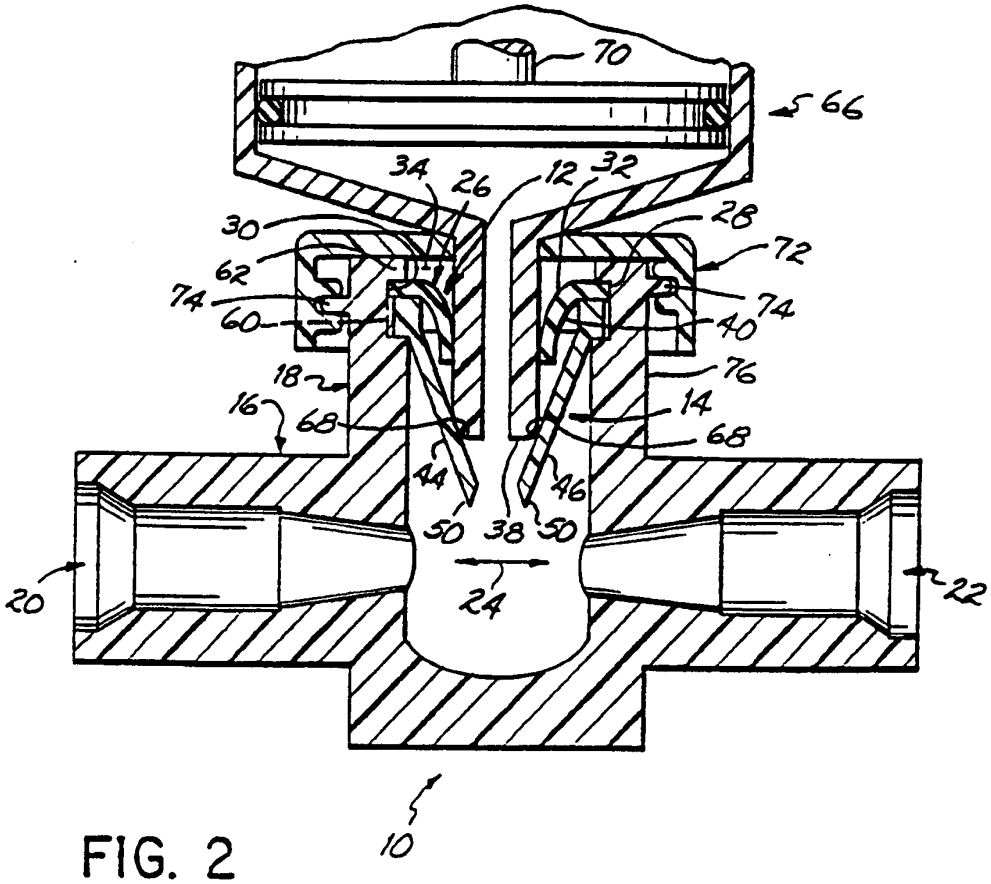
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FIG. 2

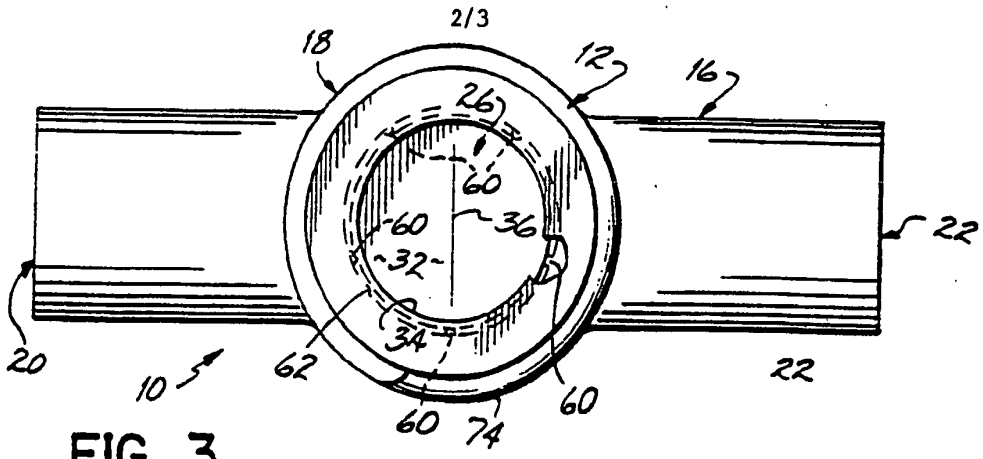
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FIG. 3

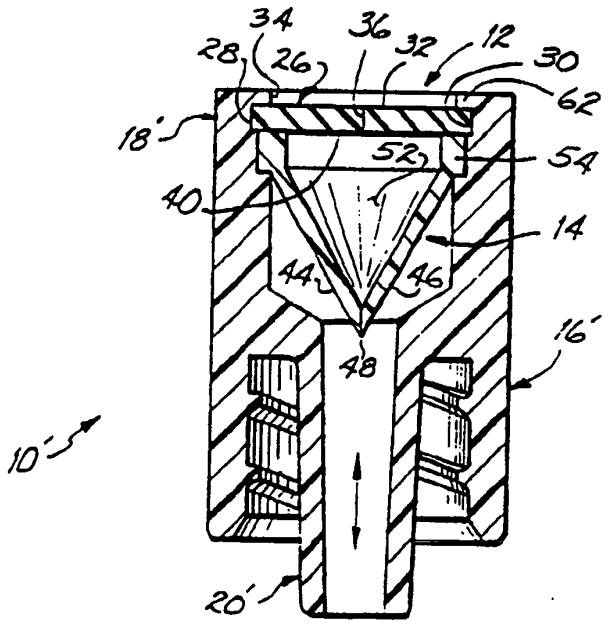
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FIG. 4

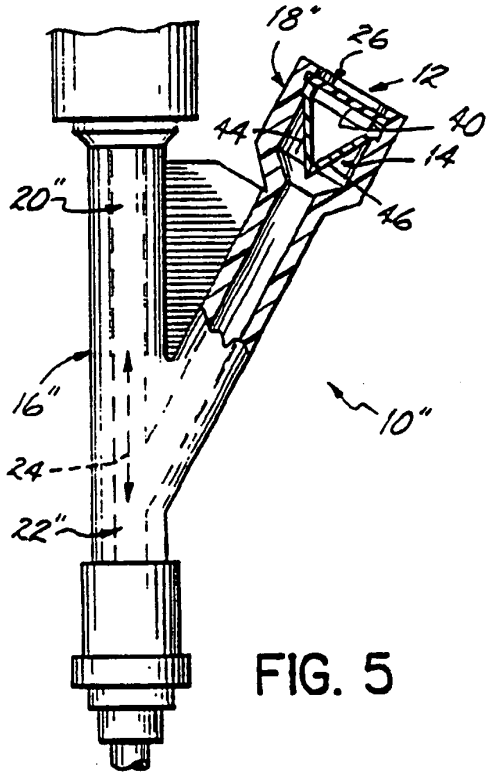

FIG. 5

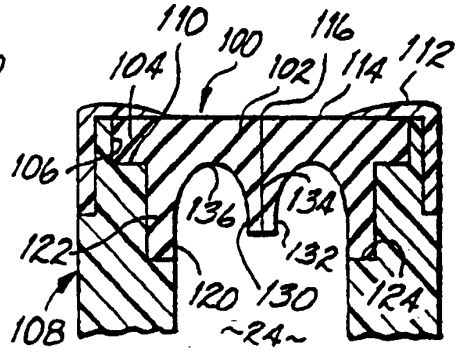

FIG. 6

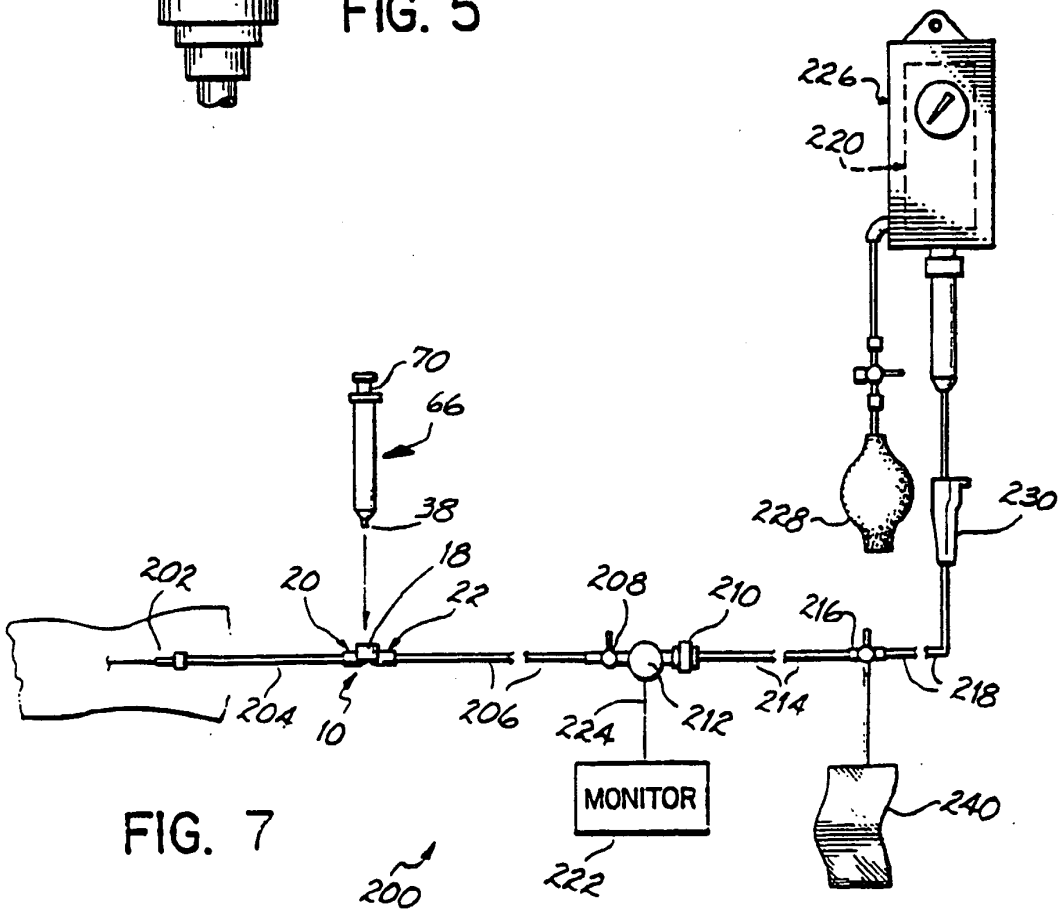

FIG. 7

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 94/13760

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/04 A61M39/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 242 393 (BRIMHALL ET AL.) 7 September 1993 see column 2, line 7 - column 3, line 33 see figures 1,4	1,2,8,9, 11,17,18
X	EP,A,0 051 718 (INTERMEDICAT GMBH.) 19 May 1982 see page 6, line 1 - page 7, line 20 see page 8, line 26 - line 28 see figures 1,2	2-4,8, 10,12,17
A		13
A	US,A,5 261 459 (ATKINSON ET AL.) 16 November 1993 see column 5, line 56 - column 6, line 18 see figure 2	5,6

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
4 April 1995	13.04.95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 94/13760

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 203 775 (FRANK ET AL.) 20 April 1993 cited in the application see column 4, line 13 - line 57 see figure 1	14,15,18

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INTERNATIONAL SEARCH REPORT

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